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May 31, 2022

### VIA ECF

Honorable Robert Kugler, U.S.D.J.  
U.S. District Court - District of New Jersey  
Mitchell S. Cohen Building & US  
Courthouse  
1 John F. Gerry Plaza, Courtroom 4D  
4th and Cooper Streets  
Camden, New Jersey 08101

Honorable Thomas I. Vanaskie (Ret.)  
Special Master  
Stevens & Lee  
1500 Market St., East Tower, Suite 1800  
Philadelphia, Pennsylvania 19103-7360

Re: ***In re Valsartan, Losartan, and Irbesartan Liability Litigation,***  
**Case No. 1:19-md-02875-RBK (D.N.J.)**

Dear Judge Kugler and Judge Vanaskie:

Please accept this letter on behalf of Plaintiffs in advance of tomorrow's case management conference.

#### **1. Plaintiffs' Proposed Schedule for Liability Expert Reports, Rule 56 Motions, and Losartan/Irbesartan Productions.**

Plaintiffs wrote to Defendants on May 19, 2022, in an effort to reach agreement on a case management plan to meet the Court's directions for moving this litigation forward. The letter, attached hereto as Exhibit 1, addressed three primary areas: (1) liability expert reports, depositions, and Daubert motions, (2) dispositive motions, and (3) Losartan and Irbesartan.

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The Parties spoke on May 27, 2022, and as discussed in more detail below, the Parties appear to largely be on different pages in their understanding of what is necessary and the Court's expectations going forward.

Plaintiffs propose a comprehensive schedule, with the exception of dates that may be impacted by the class certification rulings, as follows:

*Expert Reports*

July 18, 2022 – Plaintiffs' service of liability expert reports.

August 19, 2022 – Defendants' service of liability expert reports.

September 12, 2022 – Plaintiffs' service of rebuttal liability expert reports (if any).

September 30, 2022 – Completion of liability expert depositions

October 14, 2022 – Daubert motions filed regarding liability experts

November 7, 2022 – Responsive briefs on Daubert motions filed

November 21, 2022 – Reply briefs on Daubert motions filed

Note: Plaintiffs believe that the deadlines for the merits reports of experts whose opinions are limited solely to class issues (*i.e.*, Dr. Rena Conti, Laura Craft, and the corresponding defense experts) should be set on a schedule aligned with the disposition of *Daubert* and class certification motions.

*Dispositive Motions*

October 24, 2022 – Dispositive motions filed

December 2, 2022 – Responsive briefs on dispositive motions filed

December 23, 2022 – Reply briefs on dispositive motions filed

Note: Plaintiffs believe that the Order should contemplate the need for class notice and the scope and timing of class notice and the notice period.

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Last, Plaintiffs propose that Defendants file their respective Answers and Cross-Claims on or before June 30, 2022.

**Liability Experts:**

Defendants requested clarification as to what experts Plaintiffs see falling within this category. Plaintiffs explained that this would encompass the liability issues, including organic chemistry and the fact that the potential creation of nitrosamines should have been appreciated and tested for using available technology, cGMP issues, the broader regulatory regime, supply chain, and the damages experts in the class actions. Plaintiffs reiterated that, as recognized in their letter, those experts keyed only to class issues could be scheduled with reference to the class certification motions and their disposition, but this was an issue that would benefit from the Court's guidance as well. Defendants also asked in what cases did Plaintiffs propose to present these liability expert reports, and Plaintiffs advised this would be in the context of the master economic loss and medical monitoring complaints, and the personal injury cases.

Defendants responded that they believed the better plan would be to select a handful of personal injury cases, and serve liability and specific causation reports in just those cases. Based on the Court's clear statements on the direction of the litigation over the past few years, Plaintiffs disagreed, and expressed surprise that the Defendants continue to promote personal injury bellwether cases as the focal point. With regard to specific causation experts in individual personal injury cases, Plaintiffs agree that will be necessary, but not at this juncture at the expense of pressing forward with the parts of the litigation that have been prioritized. Adding those experts to the schedule now would unnecessarily burden the parties with an additional category of expert work. Plaintiffs pointed to the Court's statements, including those quoted below:

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Where do we go from here? I guess the next thing up are the class certification motions. And we'll do those, according to the schedule, in May. That's fine.

But I don't see, frankly, that anything else should be dependent on the outcome of those class action motions. I mean, those individuals or organizations either have a claim individually or a claim as part of a class. So they're not going to go away depending on the outcome of the motions. But I understand they're important, and we'll take care of them.

Then I foresee that there might be some summary judgment motions. There's still some legal issues out there, because some of these state laws are at play here and, you know, some states don't support certain causes of action and all that stuff. We dealt with some of that in the motions to dismiss, but there's probably some cleanup to do there.

But I will urge that the parties talk to each other, because, I mean, some of those legal issues are pretty clear and perhaps you can come to some kind of stipulation and not have to file a lot of papers.

Okay. So they're going to come. And there's no reason we have to wait for those to be filed.

And then we've talked about bellwether cases. Not my favorite things to do in the world, but there are. I'm not a big fan of them. I don't think they do much good, but, you know, we'll try them. But, you know, they can be the best of a lot of bad options in a case.

But I want to repeat something I said at the beginning of all this. I am not going to be trying any personal injury bellwether weather cases.

The personal injury cases are just too idiosyncratic for us to get the answer to the first and most important questions here, which is general causation.

So we'll pick a case if we have to, probably a third-party payor case because the damages are relatively easy to calculate in those cases, and just to get a jury to say yes or no on the question of general causation and get that done.

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I think the bottom line I'm trying to tell you, lawyers, is that I expect that my role in this will be done by the end of this year. And the logistics of that are that once I'm done what I can do is I notify the MDL panel that I'm done and request that they send the cases back where they came from or where they should have been originally filed but for the direct filing order. And they generally do that.

But that means, of course, that we lose one of the benefits of this being an MDL, that is, all of us together, all of you together in this case.

And you're going to be faced with the prospect now of simultaneous litigation in dozens and dozens of jurisdictions. There will be some cases remaining in the District of New Jersey. Well, they'll be distributed around the district also.

Of course, once the MDL part of this is done, what you're going to see -- because we've seen this in all these cases around the country, is you're going to find some hot shot plaintiff's lawyer convincing some state court judge to try some case, one of these cases, because he or she thinks they're going to get a big, broad -- big number and make a name for themselves. And there's no way that can be stopped.

We've been lucky that the state courts have been deferring to us, the federal system, while we manage this mess.

[\(2/28/2022 Tr. 40:2-42:12\).](#)

THE COURT: Well, that's fine. I mean, keep working on [*Daubert* clarification], because we're not on the cusp of filing Rule 56 motions anyway, but maybe -- maybe at the late May conference we can talk about Rule 56 motions and what your contemplations are.

Now, I understand that the motions are going to be based on the lack of an expert report as to certain claims, that's fine. But I'd also like to know if the defense is contemplating or even if the plaintiffs are contemplating any other kind of Rule 56 motions. And let's talk about that in May. Okay?

[\(4/29/2022 Tr. 14:5-14\).](#)

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Plaintiffs are eager to move this litigation, and in particular the class actions, to the point where the cases can be trial ready. It is necessary to address liability experts in order to do so, and to recognize that the liability expert opinions will cut across all three categories of cases and thus move the entire litigation forward as a whole.

**Dispositive Motions:**

Defendants have raised their desire to file dispositive motions on multiple occasions. Plaintiffs too intend to file such motions. The liability expert reports will need to be served prior to the filing of such motions since both sides will cite to the case law indicating that dispositive motions are premature before expert reports on the impacted issues are exchanged. More important, Plaintiffs are eager to reach a point of trial readiness.

During the last conference, the Court asked the Parties to provide some definition as to what dispositive motions are contemplated. Plaintiffs contemplate motions for partial summary judgment on issues including breach of express warranty, breach of implied warranty, consumer protection statutes, manufacturing defect, failure to warn/misrepresentation, and violation of cGMPs.

Defendants raised the issue of what state law the motions would be filed under (without offering any suggestion other than focusing on individual personal injury bellwether cases and the state law applicable to each individual case), and Plaintiffs responded that they would likely follow the state groupings defined in the class briefing, subject to the Court's guidance on this issue, including the possibility that the Court could ask that the motions be focused on the claims to be presented in one or more proposed class groupings against a particular manufacturer defendant or

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defendants. Plaintiffs do not see the scope of the litigation as an insurmountable impediment to dispositive motion practice and look forward to advancing to trial however the process unfolds.

**Answers:**

Plaintiffs believe that at this stage of the litigation, long after determination of the motions to dismiss and motions to amend, with liability experts and dispositive motions coming, Defendants should be required to file their Answers and any cross-claims.

Defendants advised that they believe this would be premature but did not offer a preferred time frame or rationale for waiting.

**Losartan and Irbesartan:**

Plaintiffs believe that it would be prudent for the production of documents regarding the other ARBs in this MDL to begin to roll out shortly. Plaintiffs would likely need to do little more than modify the existing requests for production to apply to Losartan and Irbesartan. The Parties have now begun resolution discussions as ordered by the Court, and it is quite unlikely that any defendant would be interested in resolving less than all of the claims brought against it. Thus, the Plaintiffs need information such as the core discovery, as with valsartan, and to know the scope and quantity of the contaminated pills sold. This will also allow for the Parties to start to develop the cases involving those drugs in case resolution cannot be reached.

Defendants predictably took the position that this would be premature and counter-productive, but offered no proposal for when they believe this would be appropriate. To the extent Defendants may suggest that this production would be burdensome, they should explain why the information related to losartan and irbesartan has not already been prepared for production, at least to a significant extent. The need for this production cannot be a surprise.

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## **2. Holding the Clarification Motions Regarding General Causation in Abeyance.**

Defendants filed a motion for clarification of the Court's *Daubert* decisions admitting the NDEA opinions of Dr. Hecht and Dr. Lagana without qualification on March 18, 2022. ([ECF 1976](#)). As previously explained, Plaintiffs planned to oppose this motion and cross-move to clarify the Order with regard to Dr. Panigrahy, which limited his NDEA opinions to pancreatic cancer, despite no limitation being stated during the Court's oral opinion.

The Court directed the Parties to meet and confer about whether these motions are necessary at this time. During the meet and confer, Plaintiffs proposed including the motions as part of the first set of relevant trial motions. Defendants explained that they intend to file an omnibus Rule 56 motion for summary judgment on personal injury claims related to NDEA and cancers other than pancreatic, and thus want to have the clarification motions decided before any Rule 56 motions based on the underlying *Daubert* decisions. Plaintiffs agreed that if the Court is inclined to allow the filing of such a motion (Plaintiffs would object to the filing of Rule 56 motion directed to specific cases at this phase), Plaintiffs would agree to hold these motions, to be heard prior to the filing of dispositive motions. This was all discussed at the last case management conference and left for further discussion.

Over the last month, Defendants never reached out to Plaintiffs to confirm or amend their initial proposal concerning these clarification motions. Plaintiffs remain prepared to discuss this issue.

## **3. Defendants' Motion for Leave to File Class Certification Surreplies.**

Defendants filed a motion to leave to file a surreply in opposition to class certification, and Plaintiffs asked the Court to strike that motion as procedurally improper. If the Court decides not



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to strike the motion, Plaintiffs plan to file a formal opposition in accordance with the Court's motion calendar.

**4. Defendants' Request for Dismissal of Paulette Silberman's Medical Monitoring Claims.**

On May 16, 2022, Defendants emailed the PEC asking for the voluntary dismissal of Paulette Silberman's medical monitoring claims. This request was based on a footnote in Plaintiffs' reply in support of the class certification of the medical monitoring claims. However, once alerted to this by Defendants, Plaintiffs reviewed that footnote and realized what was intended was not communicated, likely due to the volume of edits that were ongoing prior to submission. Plaintiffs intended to communicate that they would dismiss Mrs. Silberman's medical monitoring claims against CVS if the Court determined that those claims rendered her case unnecessarily complex, in other words, if necessary. As the Court may remember, Mrs. Silberman purchased her valsartan from QuickChek, which CVS subsequently purchased, together with its liability, and Defendants argue that this serves to exclude her as a class plaintiff. Plaintiffs do not believe this issue is difficult to address on a full record before a trial involving this specific class representative.

**5. PFS Deficiencies and Orders to Show Cause.**

Plaintiffs will be prepared to address this issue during the case management conference.

Respectfully,



ADAM M. SLATER

Cc: All counsel of record (via ECF)